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Clinical Group

Journal of Gynecological Research and Obstetrics

DOI http://dx.doi.org/10.17352/jgro.000044

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Dates: Received: 03 May, 2017; **Accepted:** 14 July, 2017; **Published:** 15 July, 2017

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Keywords: Cord milking; Delayed cord clamping; Elective cesarean section.

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Research Article

Milking Versus Delayed Cord Clamping in Full Term Neonates Delivered by Elective Caesarean Section a Randomized Controlled Trial

Abstract

Objective: The study aims to compare the short term risks and benefits of delayed cord clamping in the full term neonate delivered by caesarean section compared to milking of the umbilical cord.

Design: randomized controlled trial.

Setting: Ain Shams Maternity teaching hospital.

Patients and methods: a total of 300 pregnant women who are medically free and completed 37 weeks of gestational age (met the inclusion criteria) who attended the casualty of Ain Shams University Maternity Hospital for an elective caesarean section and completed the study.

Intervention: The patients were divided into two groups.

Group I: milking group which contains 150 patients, defined as application of a clamp to the umbilical cord after milking of the cord 5 times toward the neonate.

Group II: Late (delayed) cord clamping which contains 150 patients, defined as application of a clamp to the umbilical cord after 120 seconds of birth of the infant.

Then all the neonates will be subjected to Apgar score evaluation after 5 minutes, Hb level 6 weeks later, need for NICU and all mothers subjected to need for ICU admission, blood transfusion, need for extre-utero tonics and need for manual removal of the placenta.

Results: On comparing the two groups regarding Hb level after 6 weeks; Group I the mean Hb level was 9.95 ± 0.88 mg/dl, and Group II was 9.86 ± 0.71 mg/dl with a p value 0.338 which is not significant. In group I, 12 neonates were admitted to NICU for jaundice which represents (8%) and Group II 16 neonates were admitted to NICU for jaundice which represents (10.7%) with a p value 0.427 which is not significant.

Conclusion: For the first time in term babies, our study demonstrated that both UCM and DCC have comparable benefits in improving hematological status at 6 weeks without affecting producing any noteworthy significant adverse neonatal outcomes in initial 6weeks of life. As DCC has already been formulated as standard of care in all deliveries by American Academy of Pediatrics, UCM can be recommended in all deliveries in which DCC is not feasible or not practiced for any reason. UCM can be used in term neonates as a routine or in conditions where DCC is not feasible. In cases when the neonate requires resuscitation then UCM can be done by the neonatal team attending the baby at delivery.

Introduction

Iron deficiency and iron deficiency anemia are major public health problems in young children worldwide, and are associated with poor neurodevelopment. Delayed umbilical cord clamping has been suggested as a measure to prevent infant iron deficiency [1], but we lack data concerning its health benefits and possible adverse effects, especially in high income countries. In virtually all mammalian births, the umbilical cord remains a blood conduit from placenta to newborn for minutes to hours after birth. Potential advantages include increased neonatal blood volume and red cell mass, improved

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iron stores, more hematopoietic stem cells, and cardiovascular stability [2]. Cord clamping immediately after birth is a routine obstetric procedure in the United States [3], the definition of ``delay`` is subjective and can range from 30 to 45 seconds, 2 to 3 minutes, once the cord has stopped pulsating or after the placental birth. Arguments against early cord clamping include the reduction in the amount of placental transfusion and thus forgo any associated benefits of extra blood volume. Early cord clamping may increase the likelihood of feto-maternal transfusion (the amount of blood that is forced back across the placental barrier into the maternal circulation), as a larger volume of blood remains in the placenta. This would have been considered a potential issue prior to the introduction of Rh D immunoglobulin prophylaxis, since early clamping of the cord was considered to increase the risk. However, little work appears to have been undertaken since findings from small non-randomised studies [4], suggested there may be a reduction in feto-maternal transfusion if cord clamping was delayed [5]. Early clamping has also been associated with some higher risks for the pre-term infant. This topic is the subject of a Cochrane systematic review [6]. Delaying clamping allows time for a transfer of the fetal blood in the placenta to the infant at the time of birth. This placental transfusion can provide the infant with an additional 30% more blood volume and up to 60% more red blood cells [7], The amount of blood returned to the infant depends on when the cord is clamped and at what level the infant is held (above or below the mothers abdomen) prior to clamping [8]. The suggested neonatal benefits associated with this increased placental transfusion include higher Hb levels [9], additional iron stores and less anaemia later in infancy [10], higher red blood cell flow to vital organs, better cardiopulmonary adaptation, and increased duration of early breastfeeding [7]. There is growing evidence that delaying cord clamping confers improved iron status in infants up to six months post birth [10]. The study aims to compare the short term risks and benefits of delayed cord clamping in the full term neonate delivered by caesarean section compared with milking the umbilical cord 5 times toward the neonate in the casualties of Ain Shams University Maternity Hospital.

Patients and Methods

Randomized controlled prospective trial was conducted at the casualties of Ain Shams University Maternity Hospital comparing milking of the umbilical cord five times toward the neonate with delayed cord clamping for 120 seconds in full term neonates delivered by elective cesarean section.

Trials design: Parallel, superiority randomized controlled trial with allocation ratios 1:1.

Time: From August 2015 to February 2016.

Study Population: The study included three hundred women at the casualty of Ain Shams University Maternity Hospital, according to the following

Eligibility Criteria

1- **Inclusion criteria:** Pregnant females admitted for elective cesarean section at Ain Shams University Maternity Hospital completed 37 weeks of gestation confirmed by dates and third trimesteric ultra sound.

2- **Exclusion Criteria:**

- Known congenital anomalies of fetus (diagnosed by ultrasound).
- RH -ve mothers
- Need for urgent resuscitation for the baby.
- Multiple pregnancies (diagnosed by ultrasound).
- General anesthesia.
- Placenta previa (diagnosed by ultrasound).
- Medical disorder.

- D.M. (known diabetic on insulin treatment or random blood sugar > 200 mg/dl).

- Hypertension (known hypertensive on medication or blood pressure ≥ 140/90mm/Hg).

- Preeclampsia (blood pressure ≥ 140/90 mm/Hg + urinary albumin ≥ +1 (> 300 mg of protein in a 24 - hour urine sample).

- S.L.E. (known S.L.E. confirmed by laboratory investigation (+ve ANA, +ve Anti DNA antibodies)).

- Hepatic (known hepatic patient, Alt > 40 IU/l, Ast > 40IU/l or total bilirubin > 1.9 mg/dl).

- Renal failure (known renal failure on dialysis, BUN ≥ 20 mg/dL or S.creatinine > 1.2 mg/dl).

- Cardiac disease (rheumatic on long acting penicillin, congenital or heart failure).

- Anemic (Hb < 9 g/dl). Ethical and legal aspect

After approval of the ethics committee, an official permission was obtained from the director and the head of Obstetrics & Gynecological Department at Ain Shams the Maternity University Hospital, Egypt. The significance and purpose of the study was explained to them. Confidentiality of any obtained information was ensured to them.

Delegation of investigator responsibilities: The investigator ensured that all persons assisting with the trial are adequately informed about the protocol, any amendments to the protocol, their trial-related duties and functions. The investigator maintained a list of sub-investigators and other appropriately qualified person to whom he / she has delegated scientific trial-related duties.

Patient information and informed consent

Before being admitted to the clinical study, the patient consented to participate after the nature, scope, and possible

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consequences of the intervention has been explained in a form understandable to here. An informed consent document, in Arabic language, contains all locally required elements and specifies who informed the patient. After reading the informed consent document, the patient gave consent in writing. the patient`s consent was confirmed at the time of consent by the personally dated signature of the patient and by the personally dated signature of the person conducting the informed consent discussions. If the patient is unable to read, oral presentation and explanation of the written informed consent form and information to be supplied to patients had take place in the presence of an impartial witness. Consent was confirmed at the time of consent orally and by the personally dated signature of the patient or by local legally recognized.

Alternative (e.g., the patient`s thumbprint or mark) the witness and the person conducting the informed consent discussion was also signed and personally dated the consent document.

The original signed consent document was retained by the investigator. The investigator didn`t undertake any measures specifically required only for the clinical study until valid consent has been obtained.

Confidentiality

Only the patient number and patient initials are recorded in the CRF, and if the patient`s name appear in any other document (e.g., pathologist report), it is kept in privacy by the investigator. The investigator maintained a personal patient identification list (patient numbers with the corresponding patient named to enable records to be identified) only the investigator has this list only patient number and patient initials are used not names.

Study approval

Before the beginning of the study and in accordance with local regulation followed the protocol and all corresponding documents are declared for ethical research approval by the council of OB/GYN department, Ain Shams University. Interventions:

Before delivery all patients are submitted to:

1. Explanation of procedure to all women participating in the study.

2. Informed written Consent from every women participating in this study is administrated by the researcher.

3. All recruited women are subjected to the following:

- Complete history taking including personal history, present history, past history, menstrual history, obstetric history, medical history and family history.

- General examination

- Abdominal examination.

- Local pelvic examination.

- Abdominal ultrasound.

- Blood pressure measurement.

- Lab investigation (CBC – AST – ALT – BUN - S. Creatinine - urinary albumin - random blood sugar)

- All patients received the same dose of prophylactic antibiotics. - All women received a spinal anesthesia. The patient received good IV access and fluid preload of 500 – 1000 ml.

Then the patients is divided into two groups

Group I: Milking group which contains 150 patients, defined as application of a clamp to the umbilical cord after milking of the cord 5 times toward the neonate.

Group II: Late (delayed) cord clamping which contains 150 patients, defined as application of a clamp to the umbilical cord after 120 seconds of birth of the infant.

Method of clamping: Kocher clamp by assisting nurse 20 cm from the umbilicus of the infant. Use and timing of uterotonics (in both groups) 20 units of oxytocin slow IV infusion immediately after clamping [11].

Position of the neonate (in both groups): The neonate is positioned at a level lower than the level of the placenta.

When to stop the intervention: The intervention stopped only if severe postpartum haemorrhage (blood loss >1000 cc) or neonatal distress occurred

a- Apnoeic for > 1 minute and heart rate > 100 bpm

b- Heart rate < 60 bpm

c- Thick meconium [12].

After the operation:

- All patients were transferred to the same post-operative Ward.

- All patients received the same medication.

- All patients were nursed by well-trained nursing staff (The nursing staff being unaware to which group each patient is allocated).

LABS: Hemoglobin level by Easy Touch GCHb device

The EasyTouch®GCHb system is made for self-testing of Glucose, Cholesterol and hemoglobin levels in blood. The EasyTouch® GCHb system allows to measuring haemoglobin. The meter is made for quantitative measurement of haemoglobin levels in fresh sample of capillary blood from a fingertip. The work of the monitoring system is based on electrochemical method. It allows using the minimum amount of blood. The test results are displayed after 6 seconds for haemoglobin. The meter has the memory function. It helps

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you to analyze the changes in haemoglobin levels in blood. The measuring range for haemoglobin: 7-26 g/dl (1.1-33.3 m mo/l). Minimal sample volume for hemoglobinanalysis: 2, 6 µl. The EasyTouch®GCHb system is made for self-testing of Glucose, Cholesterol and Hemoglobin levels in blood. The EasyTouch ® GCHb system allows you to make three types of analysis with only one device. Its suitable for everyday use. The meter is made for quantitative measurement of glucose, cholesterol and hemoglobin levels in fresh sample of capillary blood from a fingertip. The work of the monitoring system is based on electrochemical method. It allows you to use the minimum amount of blood. The test results will be displayed after 6 seconds for glucose, 150 seconds for cholesterol and 6 seconds for hemoglobin. The meter has the memory function. It helps you to analyze the changes in glucose, cholesterol and hemoglobin levels in blood. The measuring range for glucose: 20-600 mg/dl (1.1-33.3 m mo/l). The measuring range for cholesterol: 100-400 mg/dl (2.6-310.4 m mo/l) the measuring range for hemoglobin: 7-26 g/dl (1.1-33.3m mo/l). Minimum sample volume for glucose analysis: 0.8 µl Minimum sample volume for cholesterol analysis: 15µl Minimal sample volume for hemoglobin analysis: 2.6µl

Outcomes

Primary: Neonatal Hb level after 6 weeks of delivery measures from heal capillary blood by (by Easy Touch GCHb device).

Secondary

1-Neonatal

- Intubation.
- Respiratory distress (intercostal, subcostal retraction, tachypnea).
- Jaundice requiring phototherapy (by history after 6 weeks of delivery).
- Neonatal Intensive Care unit (NICU) admission (for causes other than photo therapy).
- Apgar score (after 5 minutes of delivery).

2-Maternal

- Need for blood transfusion.
- Additional need for therapeutic uterotonics (more than 20 units of oxytocin).
- Post-partum hemorrhage (blood loss > 500cc).
- Intensive Care unit admission.

Statistical Methods

Data is collected, tabulated, then analyzed using IBM© SPSS© Statistics version 22 (IBM© Corp., Armonk, NY).

Results

The mean age of included for women in Group I was 22.42±1.67years and 22.4 ± 1.78 in Group II (range: 18 – 40 years). There were no significant differences between women of both groups regarding age, parity and gestational age, and if the patient was primisection or previous section (table 1). Table 2 shows the neonatal outcomes and comparing both groups as regard intubation, respiratory distress, clinical jaundice, and Phototherapy and NICU admission with no significant difference between the two groups. There was no significant difference in neonatal Hb after 6 weeks of delivery in both groups (table 3). Table 4 shows no significant difference in maternal outcome as regard blood transfusion, manual removal of the placenta, use of therapeutic uterotonics, and post-partum Hemorrhage.

Discussion

Iron is essential for several aspects of brain development, including myelination, dendritogenesis, neurotransmitter function, and neuronal and glial energy metabolism [13]. Iron deficiency anemia in young children is associated with long lasting cognitive and behavioural deficits [14]. Iron deficiency

Table 1: Difference between the two groups regarding demographic date.

	Group 1	Group 2	P Value
Age (Years)	22.4±1.78	22.42±1.67	0.893 NS
Parity	3.04±0.84	2.92±0.84	0.215 NS
Previous section	115(76.7%)	108(72%)	0.355 NS
Gestation age (Weeks)	38.6.6±0.67	38.8±0.5	0.857 NS

Data presented as number (percentage) NS non-significant

Table 2: Difference between both groups as regard neonatal outcomes in both groups.

	Group 1	Group 2	P Value
Gender (Male)	66(44%)	70(46.7%)	0.643 NS
Intubation	0	0	
Respiratory Distress	1 (0.7%)	3 (2%)	0.622 NS
Clinical Janudice Requiring phototherapy	16 (10.7%)	12 (8%)	0.427 NS
NICU admission For causes other than photo therapy	1 (0.7%)	3 (2%)	0.622 NS
APGAR Score	8.37±0.58	8.26±0.66	0.175 NS

Data presented as number (percentage) Nicu nenatal intensive care unit Analysis using Chi-Squared Test NS non-significant

Table 3: Showing difference in neonatal Hb after 6 weeks of deliveryin both groups.

	Group 1	Group 2	P Value
Hb (gm/dl)	9.95±0.88	9.86±0.71	0.338 NS

Data presented as number (percentage) NS not significant

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Table 4: Showing difference in maternal outcome as regarde blood transfusion, manual removal of the placenta, use of therapeutic uterotonics and post-partum hemorrhage.

	Group 1	Group 2	P Value
Blood Transfusion	1 (0.7%)	2 (1.3%)	0.624 NS
Manual Removal of the placenta	3 (2%)	2 (1.3%)	1 NS
Therapeutic Uterotonics	8 (5.3%)	10 (6.7%)	0.809 NS
Post-partum hemorrhage (>500cc)	4 (2.7%)	2 (1.3%)	0.684 NS
ICU Admission	0	0	0

Data persented as number (percentage)
NA not significant
ICU intensive care unit

without established anemia has also been associated with altered affective responding, impaired motor development, and cognitive delays [15].

Two recent meta-analyses have concluded that iron supplementation improves psychomotor and mental development in infants and children. Thus, the available evidence suggests that it is important to prevent iron deficiency in infants in order to achieve optimal brain development [16].

In virtually all mammalian births, the umbilical cord remains a blood conduit from placenta to newborn for minutes to hours after birth. Potential advantages include increased neonatal blood volume and red cell mass, improved iron stores, more hematopoietic stem cells, and cardiovascular stability [2].

This study was performed among Egyptian patients whose offspring have a baseline increased risk for developing neonatal and childhood anemia. We demonstrated that in full term neonates, the hematological and hemodynamic effects of repeated umbilical cord milking (UCM) with early cord clamping were similar to those of delayed cord clamping (DCC) after 120 seconds of birth. Both interventions led to comparable hemoglobin level at 6 weeks of age without any significant side effects in initial 6 weeks of life. There have been many trials demonstrating the benefits of DCC on the hematological status in term babies but there have limited trials looking at the benefits of UCM in general and especially in term neonates. It was reported for the first time that DCC has beneficial effects on hemoglobin level of the neonate when he serially assessed them till 96 hours of life [17].

Also demonstrated that umbilical cord clamping after cessation of cord pulsations resulted in increase in hemoglobin at 2 months of age [18]. Another study also demonstrated that mean hemoglobin at 3 months of age was significantly higher in DCC group [19]. The largest trial to evaluate the effect of DCC was done on 476 term babies. They did serial evaluation of hematological parameters from birth till 6 months of age and reported higher mean corpuscular volume, ferritin, body iron and stored iron [10]. No study has evaluated whether the advantage in hematological parameters persist beyond 6 months of age.

The Cochrane meta-analysis of 11 trials on the effect of timing of umbilical cord clamping in term infants analyzed both maternal and fetal outcomes. Reviewers found no significant effect on postpartum hemorrhage. The infants who were subjected to DCC had significantly higher hemoglobin by 2.17 gm/dl (95 % CI, 0.28 - 4.06) and higher ferritin by 11.8 ng/ml (95 % CI, 4.07 - 19.53) till 6 months of age [3].

The result of an earlier meta-analysis was also similar to the Cochrane meta-analysis. The above findings are comparable to the results of our study though we evaluated our babies at an earlier age of one and a half months. The high and comparable levels of hemoglobin in the newborns of both the groups in our study is probably due to increased blood transfusion from the placenta and cord to the neonate at birth whose benefits extend in to early infancy. In view of various studies demonstrating the benefits of DCC, the American Academy of Pediatrics (AAP) has recently recommended that cord clamping should be delayed by at least 1 minute in uncomplicated deliveries of both term and preterm neonates not requiring resuscitation [20].

A randomized controlled trail on very preterm infants of 26-29 weeks of gestation and compared UCM to early cord clamping. They demonstrated higher hemoglobin, decreased number of RBC transfusions and shorter duration of ventilation or supplemental oxygen in the milked group [21].

A larger randomized controlled trial on 200 term babies also reported that UCM after birth leads to higher hemoglobin and better iron status at 6 weeks of age as compared to babies receiving early cord clamping [22]. Also, it was [6], reported a higher hemoglobin levels than previously reported [22], which was possibly related to the milking technique.

In UCM group we cut end clamped the cord as soon as possible to minimize the time before clamping and excluded the baby if this time exceeds 30 seconds. We have no data for the mean time taken to cut and clamp the cord in UCM group. Most studies including those mentioned above have compared either UCM [22]. or DCC (2, and 20), to early cord clamping in term neonates. However, there are only limited trials directly comparing the effects of DCC and UCM in term neonates [6].

They had randomized relatively small number of 58 preterm infants less than 33 weeks of gestation and reported that both procedures are equally efficacious in improving hemoglobin soon after birth and at 6 weeks of life. Though we also found similar results in term babies, the methodology of the above mentioned trial and ours differed in terms of time of clamping, frequency of cord milking as well as position of the baby after delivery. The time to delay cord clamping by Rabe et al was 30 seconds after birth in delayed cord clamping group [6]. We followed the methodology of umbilical cord milking and positioning of baby being held after delivery as in our published earlier by our group [22]. Theoretically, delaying the cord clamping for a longer period of time should lead to more passage of trans-cord blood than milking due to connectivity to bigger pool of blood in placenta. However, this has not been observed and hemoglobin level in both the groups was found to be comparable in the two studies.

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In another study, the above parameters were found to be significantly higher at 7 hours in the delayed clamping group [10]. In another randomized controlled trial from Argentina, newborns were randomly assigned to cord clamping within the first 15 seconds, at 1 minute, and at 3 minutes after birth. The prevalence of anemia, as defined by hematocrit levels less than <45% at 6 hours, was significantly lower in later two groups than in first group but mean hematocrit level remained within physiologic limits in all the three groups [23].

However, two studies from the Indian subcontinent reported comparatively lower level of hemoglobin during the initial 48 hours of life in both control and intervention arm when compared to studies conducted in developed countries. This could be due to poor maternal health and higher prevalence of maternal iron deficiency in developing countries [22, 24].

The proportion of babies requiring phototherapy in either group of our study was not only similar, but also not different from need for phototherapy in other reports [25]. The present study did not find any baby with symptomatic polycythemia, respiratory distress or need for admission in NICU for reason other than jaundice. Other trials [22, 23] and meta-analysis [3, 20] also have not reported any increase in above mentioned side effects with the two methods due to increase in cord blood flow into the baby.

The effect of cord clamping in term births was assessed on maternal and fetal outcomes in 11 clinical trials involving 2,989 mothers and their babies. Reviewers found no significant differences in postpartum hemorrhage between the early cord-clamping (clamping within 1 minute after birth) and late cord-clamping groups (clamping at least 1 minute after birth or after cessation of cord pulsation) in any of the five trials (2,236 women) that measured this outcome (relative risk [RR] for postpartum hemorrhage 500 ml or more, 1.22; 95 % confidence interval [CI], 0.96 to 1.55). No significant differences were found in other neonatal outcomes such as Apgar score less than seven at 5 minutes (two trials, 1342 neonates), admission to special care baby nursery or neonatal intensive care unit (three trials, 1293 infants), respiratory distress (four trials, 1387 infants) [20].

Another study assessed the effect of cord clamping in term births on maternal and neonatal outcomes in 15 clinical trials involving 3,911 mothers and their babies. Reviewers found no significant difference between early and delayed cord clamping as regard maternal (Need for blood transfusion, additional need for therapeutic uterotonics, Post-partum hemorrhage (blood loss > 500cc) and ICU admission), and neonatal(intubation, respiratory distress, clinical jaundice, neonatal Intensive Care unit (NICU) admission, and Apgar score (after 5 minutes of delivery) [26].

The main strength of our study was that it was a randomized controlled trial with appropriate sample size and several neonatal outcomes like Apgar score at 5 minutes and maternal outcomes. Our study has few limitations also. Our study had a short duration of follow up. A longer follow up till 6 to 12 months of age is desirable to establish whether the initial advantage in hemoglobin sustains later in infancy and early childhood. Another limitation of our study is the further management of the jaundice in the NICU and the onset time and the cause of the jaundice. Other limitations included iron stores measurement and relation between cord Hb and its relation to 6 weeks Hb lack of blinding, limited generalizability and the lack of power for rare adverse outcomes.

Conclusion & Recommendations

For the first time in term babies, our study demonstrated that both UCM and DCC have comparable benefits in improving hematological status at 6 weeks without affecting producing any noteworthy significant adverse neonatal outcomes in initial 6weeks of life. As DCC has already been formulated as standard of care in all deliveries by American Academy of Pediatrics, UCM can be recommended in all deliveries in which DCC is not feasible or not practiced for any reason.

UCM can be used in term neonates as a routine or in conditions where DCC is not feasible. In cases when the neonate requires resuscitation then UCM can be done by the neonatal team attending the baby at delivery.

Implication for research

Further studies with longer follow-up are needed to establish the sustainability of the advantage in hemoglobin later in infancy. Other parameters like cerebral oxygenation, cerebral blood volume and serum ferritin could also have been further evaluated. Also, superior venacaval flow indices & ECHO can be studied to seen the impact of extra volume transfused on the cardiac function of the baby.

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Citation: El-kotb AM (2017) Milking Versus Delayed Cord Clamping in Full Term Neonates Delivered by Elective Caesarean Section a Randomized Controlled Trial J Gynecol Res Obstet 3(3): 079-085. DOI: http://dx.doi.org/10.17352/jgro.000044